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10/663,909	09/17/2003	Julian A. Quintero	CMED.10022	2640
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PO BOX 31686			HUYNH, KHOA D	
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SHORTENED STATUTOR	RY PERIOD OF RESPONSE	. MAIL DATE	DELIVERY MODE	
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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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	Application No.	Applicant(s)			
	10/663,909	QUINTERO ET AL.			
Office Action Summary	Examiner	Art Unit			
	Khoa D. Huynh	3751			
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the o	correspondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period value of the provision of the period for reply within the set or extended period for reply will, by statute, any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be the will apply and will expire SIX (6) MONTHS from the cause the application to become ABANDONE	N. mely filed the mailing date of this communication. ED (35 U.S.C. § 133).			
Status					
1) Responsive to communication(s) filed on 16 Fe 2a) This action is FINAL. 2b) This 3) Since this application is in condition for alloware closed in accordance with the practice under E	action is non-final. nce except for formal matters, pre				
Disposition of Claims					
4) ☐ Claim(s) 2-18,20-44 and 47-52 is/are pending 4a) Of the above claim(s) 17,18,29-36 and 47-4 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 2-16,20-28,37-44,51 and 52 is/are rej 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/o	4 <u>9</u> is/are withdrawn from conside ected.	ration.			
Application Papers					
9)☑ The specification is objected to by the Examine 10)☑ The drawing(s) filed on 9/17/03;10/17/05;02/16 Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11)☐ The oath or declaration is objected to by the Ex	$\frac{1}{07}$ is/are: a) \square accepted or b) \square drawing(s) be held in abeyance. So tion is required if the drawing(s) is of	ee 37 CFR 1.85(a). ojected to. See 37 CFR 1.121(d).			
Priority under 35 U.S.C. § 119					
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 					
Attachment(s)	.	(DTO 448)			
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	4) Interview Summar Paper No(s)/Mail I Notice of Informal 6) Other:	Date			

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DETAILED ACTION

1. Applicant's request for reconsideration of the finality of the rejection of the last

Office action is persuasive and, therefore, the finality of that action is withdrawn.

Drawings

- 2. The drawings of Figure 16 were received on 02/16/2007. These drawings are not acceptable since they contain new matter. Firstly, the new Fig. 16 shows the arcuate camming surfaces. These arcuate camming surfaces constitute new matter. Applicant's original disclosure does not describe the camming surfaces as arcuate. In addition, even though camming surfaces are known to those of skill in the art, the camming surface should not be limited to the arcuate surfaces since there are different camming surfaces. And lastly, the new Fig. 16 shows a plurality of containers 446. The plurality of containers constitutes new matter. Applicant indicates in the remarks that support for the new figure may be found in paragraph [0099]. However, after a full review of paragraph [0099], the support for the new figure could not be found.

 Paragraph [0099] simply states, "a kit may...include at least one applicator/dispenser 400 and a plurality of frangible ampoules 446." Paragraph [0099] does not disclose a plurality of containers placed partially in the cavity of container as claimed in claim 37 and shown in new Fig. 16.
- 3. The drawings, especially the elected Figures 10-15, are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the camming surface as recited in claim 20, a plurality of containers as recited in claim 37; a plurality of removable applicator tips as recited in claim 38, at

least two of the plurality of containers contain different amounts of adhesive material as recited in claim 43; at least two of the plurality of containers contain a different adhesive material as recited in claim 44 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: a second container as recited in claim 4.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. Each of the claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims calls for "a camming surface arranged on the second body portion" for moving the breaking member into the cavity. Nevertheless, such claimed subject matter is inaccurate and lack of support. As disclosed, in the instant specification, paragraph [0093], corresponding camming surfaces or inclined ramps 411 locate on an inner surface of the second body and press the breaking member 416 into the ampoule. The disclosure does not describe a camming surface arranged on the second body and pressed the breaking member 416 into the ampoule. Since the claimed subject matter was not described in the specification, claim 20 fails to comply with the enablement requirement.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 20 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 calls for "a camming surface arranged on the second body portion" for moving the breaking member into the cavity. Such recitations render the claims indefinite since such recitations do not have detailed supports in the instant specification. Since each of the claims does not clearly set forth the metes and bounds of the patent protection desired, the scope of each of the claims is unascertainable.

Claim 21 depends on claim 20 and is likewise indefinite.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 7. Claims 2-5, 20, 21, 22-24, 26-28, 51 and 52, as presently and best understood, are rejected under 35 U.S.C. 102(a)/102(e) as being anticipated by Hoang et al. (2002/0076255).

Regarding claim 2, the Hoang et al. reference discloses an applicator/dispenser assembly (Figs. 14-17) that is capable of being used to

apply a polymerizable monomeric adhesive material. The assembly includes a first body portion (constitute by the handle) and a second body portion (constitute by the portion with element 30). The first and second body portions are movable relative to one another. A cavity forms in at least one of the first and second body portions. A breaking member (24) arranged in the first body portion (Fig. 15), wherein movement (when the portions assembled) of one of the body portions moves the breaking member into the cavity. The breaking member includes a two opposing members (24,24) such that both opposing members are moved into the cavity upon movement of the body portions.

Regarding claim 51, the assembly also includes a visual indicator (constitute by the outer flange member on the first portion) that indicates movement of one of the body portion relative to another from an initial position.

Regarding claim 3, the Hoang et al. reference discloses an applicator/dispenser assembly (Figs. 14-17) that is capable of being used to apply a polymerizable monomeric adhesive material. The assembly includes a first body portion (constitute by the handle) and a second body portion (constitute by the portion with element 30). The first and second body portions are movable relative to one another. An open space forms at least partially in and between the first and second body portions. A breaking member (24) arranged in the first body portion (Fig. 15), wherein movement (when the portions assembled) of one of the body portions moves the breaking member into the open space. A container (25) is at least partially disposed within the open space, wherein

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movement (when the portions assembled and in use) of one of the body portions moves the breaking member to rupture the container (Fig. 17).

Regarding claim 52, the assembly also includes a visual indicator (constitute by the outer flange member on the first portion) that indicates movement of one of the body portion relative to another from an initial position.

Regarding claims 4 and 5, as best understood, the assembly also includes a second container (constitute by the thicker body portion of element 24) having at least one opening. The second container surrounds the container, wherein movement of one of the body portions moves the breaking member to rupture the container without breaking the second container. As schematically shown in Figure 17, the second container including an open hole.

Regarding claims 20 and 21, the Hoang et al. reference discloses an applicator/dispenser assembly (Figs. 14-17) that is capable of being used to apply a polymerizable monomeric adhesive material. The assembly includes a first body portion (constitute by the handle) and a second body portion (constitute by the portion with element 30). The first and second body portions are movable relative to one another. A cavity forms in at least one of the first and second body portions. A breaking member (24) arranged in the first body portion (Fig. 15), wherein movement (when the portions assembled) of one of the body portions moves the breaking member into the cavity, wherein the second body portion is rotatable relative to the first body portion. A camming surface (constitute by the portion of one of the body portion having threads) is arranged

on the second body portion, wherein rotation of the second body portion moves the breaking member into the cavity by contacting the camming surface and the breaking member. The breaking member includes a two opposing members (24,24) such that both opposing members are moved into the cavity upon movement of the body portions.

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Regarding claims 22-24 and 26-28, the Hoang et al. reference discloses an applicator/dispenser assembly (Figs. 14-17) that is capable of being used to apply a polymerizable monomeric adhesive material. The assembly includes a first body portion (constitute by the handle) and a second body portion (constitute by the portion with element 30). The first and second body portions are movable relative to one another. An open space forms at least partially in and between the first and second body portions. A breaking member (24) arranged in the first body portion (Fig. 15), wherein movement (when the portions assembled) of one of the body portions moves the breaking member into the open space. A container (25) is at least partially disposed within the open space, wherein movement (when the portions assembled and in use) of one of the body portions moves the breaking member to rupture the container (Fig. 17). The assembly also includes a bladder (constitute by the thicker body portion of element 24 and the chamber of the portion having a filter [0044]) with at least a portion of the bladder is flexible. The second container surrounds the container, wherein movement of one of the body portions moves the breaking member to rupture the container without breaking the second container. As schematically shown in

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Figure 15, a plug member (constitute by filter taught in paragraph [0044]) is at least partially disposed in an opening of the bladder, wherein it is inherently that the plug member is made of material that is porous. The plug member also includes a removable tip (at 30).

Claim Rejections - 35 USC § 103

- 8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 9. Claims 6-16, are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoang et al. (as discussed supra).

Regarding claims 6-8, the Hoang et al. reference DIFFERS in that it does not disclose the specific types of adhesive material as claimed, it, however, would have been obvious to one of ordinary skill in the art at the time the invention was made to have used such types of adhesive material for the Hoang et al. dispenser. Such modification would be considered a mere choice of preferred types of adhesive material on the basis of its suitability for the intended use.

Regarding claim 9, the Hoang et al. reference DIFFERS in that it does not disclose the specific material for the container as claimed, it, however, would have been obvious to one of ordinary skill in the art at the time the invention was made to have used such material to made the container of the Hoang et al.

dispenser. Such modification would be considered a mere choice of a preferred material for a container on the basis of its suitability for the intended use.

Regarding claims 10-16, the Hoang et al. reference discloses an applicator/dispenser assembly having substantially all features as claimed, except for the specific material of the cavity. It, however, would have been obvious to one of ordinary skill in the art at the time the invention was made to have used such material to form the cavity of the Hoang et al. dispenser. Such modification would be considered a mere choice of a preferred material for forming a cavity on the basis of its suitability for the intended use.

Regarding claim 25, the Hoang et al. reference DIFFERS in that it does not disclose that the plug member including a medicament as claimed, it, however, would have been obvious to one of ordinary skill in the art at the time the invention was made to have applied such liquid treatment to the plug member of the Hoang et al. dispenser. Such modification would be considered a mere choice of a preferred liquid disinfectant for a plug member on the basis of its suitability for the intended use, especially since the Hoang et al. dispenser is being used a an disinfectant applicator.

10. Claims 37-44, as best understood, are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoang et al (as discussed supra) in view of Voiers et al. (6425704).

As discussed supra, the Hoang et al. reference discloses an applicator/dispenser assembly having substantially all features as claimed, except for a kit as claimed. Attention, however, is directed to the Voiers et al.

reference which discloses another applicator/dispenser assembly including a plurality of containers and applicator tips forming a kit (col. 10, lines 24-40). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the Hoang et al. reference by employing a plurality of containers and applicator tips forming a kit, as taught by Voiers et al., to allow the user of the applicator the ability to select a desired applicator for a particular application.

Response to Amendment

11. Applicant's amendment, filed on 02/16/07, to the pending claims is insufficient to distinguish the claimed invention from the cited prior art or overcome the rejections as discussed above.

Response to Arguments

12. Applicant's arguments filed on 02/16/07 with respect to the pending claims have been fully considered. However, they are deemed not persuasive.

<u>Drawings</u>

Firstly, none of the previously elected Figures 10-15 and new Figure 16 shows a plurality of removable applicator tips as recited in claim 38. Applicant points to paragraphs [0044], [0056], [0061], [0066], [0069] and [0083] and Figures 1, 10 and 11 and asserts that the removable tips are described and shown. Nevertheless, none of Figures 1, 10 and 11 individually shows a plurality of removable applicator tips.

removable applicator tips may be used in the embodiment of Figures 13-15. Therefore, the objection is sustained.

And lastly, under 37 CFR 1.83(a), the drawings must show every feature of the invention specified in the claims. Therefore, the at least two of the plurality of containers contain different amounts of adhesive material as recited in claim 43 and at least two of the plurality of containers contain a different adhesive material as recited in claim 44 must be shown or the features canceled from the claims.

Specification

Applicant asserts in the remarks section that the second container is element 447. Nevertheless, element 447 is disclosed in the instant disclosure as a tube. If applicant intends to designate element 447 to be "a second container", then the following changes are recommended: in paragraph [0096], line 1 should be changed to read --the tube or second container 447 is designated to contain...--.

Rejections

Applicant also asserts that Hoang et al. reference does not teach the movement of one of the first and second body portions relative to the other moves the breaking member into the cavity as claimed in claim 2. See remarks section, page 19. The examiner disagrees. As stated in the above rejection, Hoang et al. does teach an applicator/dispenser assembly (Figs. 14-17) having a first body portion (constitute by the handle) and a second body portion (constitute by the portion with element 30), and a breaking member (24) arranged in the first body portion (Fig. 15), wherein the movement (when the portions assembled together) of one of the body portions relative

to the other moves the <u>breaking member into the cavity</u>. Claim 2 does not call for moving the breaking member into the cavity <u>to rupture the container</u> as argued by applicant.

Applicant further asserts that Hoang et al. does not teach the movement of one of the first and second body portions relative to the other moves the breaking member into the cavity to rupture the container as claimed in claims 3 and 22. See remarks section, page 20. The examiner disagrees. As stated in the above rejection, Hoang et al. does teach an applicator/dispenser assembly (Figs. 14-17) having a first body portion (constitute by the handle) and a second body portion (constitute by the portion with element 30), and a breaking member (24) arranged in the first body portion (Fig. 15), wherein the movement of one of the body portions (when in use, the wall of the handle of moved inwardly by external pressure) relative to the other moves the <u>breaking</u> member into the cavity to rupture the container.

Applicant further argues that Hoang et al. reference does not teach the rotation of second body portions relative to the first body portion moves the breaking member into the cavity as claimed in claim 2. See remarks section, page 20. The examiner disagrees. As stated in the above rejection, Hoang et al. does teach an applicator/dispenser assembly (Figs. 14-17) having a first body portion (constitute by the handle) and a second body portion (constitute by the portion with element 30), and a breaking member (24) arranged in the first body portion (Fig. 15), and a camming surface (constitute by the portion of one of the body portion having threads) is arranged on the second body portion, wherein rotation of the second body portion moves the

breaking member into the cavity by contacting the camming surface and the breaking member. Claim 20 does not call for moving the breaking member into the cavity to rupture the container as argued by applicant.

Therefore, Hoang et al. does teach applicant's invention as claimed.

Similar arguments could be made for other rejections in view of the reasons explained supra.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khoa D. Huynh whose telephone number is (571) 272-4888. The examiner can normally be reached on M-F (7:00-3:30).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory Huson can be reached on (571) 272-4887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Khoa D. Huynh Primary Examiner Art Unit 3751

HK 03/15/2007